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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,721	03/19/2004	Paul Birkmeyer	101896-0240	2720

21125 7590 10/17/2006

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EXAMINER
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SWIGER III, JAMES L

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/708,721	BIRKMEYER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	James L. Swiger	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 14-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/22/04;9/22/06;7/10/06</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group II (claims 14-29) in the reply filed on 7/10/2006 is acknowledged.

Claims 1-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/10/2006.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Spitler et al. (US Pub 2005/0085813). Spitler et al. disclose a spinal system having an access device with an inner lumen (13c) that extends between the proximal and distal ends, with at least an opening formed in the sidewall (Fig. 2c, 401). Spitler also disclose a spinal fixation element (Fig. 9) that has a feature (91) that is further considered at least bulbous and is considered to extend radially outward and is larger than at least the width of a one opening in the access device. The fixation element also is elongate and

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has at least one end substantially flattened (92) and has a feature that is sized to prevent passage thereof through the at least one opening in the access device (see Figs. 8a and 8b). The opening of the access device extends from the distal end of the access device and terminates distal to the proximal end of the access device. The opening is capable of having a length that is greater than the fixation element, depending on the size of the fixation element. The device also has opposed openings (see Fig. 2E) and a pusher member that has an elongate shaft (42), that is slidably disposable within the extends into the at least one opening in the sidewall. The pusher member also is a capable of allowing a portion of the spinal fixation element to extend through at least one opening in the sidewall (see Fig 7A, showing the displacement of the anchor). The kit also has an actuating member that is able to move a pusher or a device connected to the spinal anchor.

Claims 1-2, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Allard (US Patent 5,484,440). Allard discloses device for bone or spine fixation having an access device (see Fig. 9) with an inner lumen (26), and at least one opening formed in a sidewall (see approx. 54 in Fig. 6) and may be considered two or opposing, a spinal fixation element (38) having a feature (56) that is considered bulbous and is sized in combination with portion 36 to prevent passage through the at least one opening of the device. Allard also comprises a shaft (16) and a pusher member (26) that extends into the at least one opening in the sidewall.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allard '440 in view of Taylor et al. (US Patent 6,267,765). Allard discloses the claimed invention except for a spinal implant where one end has a substantially flattened portion and also has a protrusion that extends radially outward. Taylor et al. discloses a flattened portion (21) and a radial, outwardly-projecting portion (14) that aid in the spinal anchor's placement relative to the device (see Col. 5, lines 8-35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Allard having at least a partially flattened portion on the spinal anchor and a radial, outwardly-projecting portion in view of Taylor to better secure the anchor and use the device.

Claims 5-7 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allard '440 in view of Boehm, Jr. et al. (US Pub 2004/0039384). Allard discloses the claimed invention except for an opening in the access device that extends from the distal end and terminates distal to the proximal end, an opening that is greater than a spinal fixation element, and a pusher member that is slidably disposable in the access device and an actuating member (116, par 0058). Boehm, Jr. et al also disclose an opening in the sidewall (Fig. 11, that may be greater than the length of a spinal fixation element, depending on the size of the element), and terminates distal to the proximal

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end allowing proper displacement of the spinal fixation items (Page 7, par 0067). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Allard having at least an opening that terminates distal to the proximal end and an opening greater than the fixation element and an actuator to better use the device in surgery.

### ***Conclusion***


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 9/30/06

JLS

  
EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER